METHOD FOR DETERMINING THE EFFECTIVE THERMAL MASS OF A BODY OR ORGAN USING A COOLING CATHETER

Cross-Reference to Related Applications

This application is a continuation of co-pending U.S. Patent Application Serial No. 10/082,964, filed on February 25, 2002, entitled "Method For Determining The Effective Thermal Mass Of A Body Or Organ Using A Cooling Catheter", which is a continuation of U.S. Patent Application Serial No. 09/586,000, filed June 2, 2000, entitled "Method for Determining the Effective Thermal Mass of a Body or Organ Using a Cooling Catheter".

Background of the Invention

I. Field of the Invention

The present invention relates generally to the modification and control of the temperature of the whole body or a selected body organ. More particularly, the invention relates to a method for controlling whole body or organ temperature by selecting an appropriate gain based on the mass of the body or organ.

II. Description of the Related Art

Organs in the human body, such as the brain, kidney and heart, are maintained at a constant temperature of approximately 37° C. Hypothermia can be clinically defined as a core body temperature of 35° C or less. Hypothermia is sometimes characterized further according to its severity. A body core temperature in the range of 33° C to 35° C is described as mild hypothermia. A body temperature of 28° C to 32° C is described as moderate hypothermia. A body core temperature in the range of 24° C to 28° C is described as severe hypothermia.

Hypothermia is uniquely effective in reducing brain injury caused by a variety of neurological insults and may eventually play an important role in emergency brain resuscitation. Experimental evidence has demonstrated that cerebral cooling improves outcome after global ischemia, focal ischemia, or traumatic brain injury. For this reason, hypothermia may be induced in order to reduce the effect of certain bodily injuries to the brain as well as other organs.

Catheters have been developed which are inserted into the bloodstream of the patient in order to induce total body hypothermia. For example, U.S. Patent No. 3,425,419 to Dato describes a method and apparatus of lowering and raising the temperature of the human body. The Dato invention is directed towards a method of inducing moderate hypothermia in a patient using a metallic catheter. The metallic catheter has an inner passageway through which a fluid, such as water, can be circulated. The catheter is inserted through the femoral vein and then through the inferior vena cava as far as the right atrium and the superior vena cava. The Dato catheter has an elongated cylindrical shape and is constructed from stainless steel. By way of example, Dato suggests the use of a catheter approximately 70 cm in length and approximately 6 mm in diameter. However, use of the Dato invention implicates certain negative effects of total body hypothermia.

Due to certain problems associated with total body hypothermia, attempts have been made to provide more selective cooling by intravascularly regulating the temperature of a selected organ. For example, a heat transfer element such as disclosed in Appl. Serial No. 09/103,342 may be placed in the feeding artery of the organ to absorb or deliver the heat from or to the blood flowing into the organ. The transfer of heat may cause either a cooling or a heating of the selected organ. The heat transfer element is small enough to fit within the feeding artery while still allowing a sufficient blood flow to reach the organ in order to avoid ischemic organ damage. By placing the heat transfer element within the feeding artery of an organ, the temperature of an organ can be controlled without significantly affecting the remaining parts of the body.

The human thermoregulatory system usually maintains a core body temperature near 37°C but during induced anesthesia, the patient's thermoregulatory defense mechanisms are inhibited. This inhibition lowers the patient's threshold for vasoconstriction and shivering so that the patient losses the ability to control his or her core temperature. In this state of anesthesia, hypothermia can arise from environmental factors, the exposure of body cavities, and the use of active cooling devices. As a result, anesthetized patients are poikilothermic, with body temperatures determined by the environment, over about a 4°C range of core temperatures.

External cooling/rewarming devices are currently used in surgical procedures to induce hypothermia or to return to normothermic conditions after hypothermia. These devices transport heat flux through the skin, which is an ineffective way to achieve heat transfer because as a result of the different vasoconstrictive states of the patient, blood may not be communicating from the core to the periphery. Endovascular core cooling/rewarming techniques can be much more effective in altering the temperature state of the patient. However, with enhanced effectiveness comes the need to control the degree of heat transfer that is provided to induce, control, and maintain the desired thermal state. Ideally, a heat balance can be achieved by a closed loop feedback system in which the patient's core temperature is sensed and continuously monitored with a standard disposable temperature probe. The temperature is fed back to a controller, which alters the rate of heat transfer through the endovascular catheter, thus achieving the desired temperature state of the patient.

Various feedback control algorithms can be used to control the rate at which heat is extracted from or delivered to the body. In this way the temperature of the body or organ can be varied at a controlled rate and/or maintained at a desired temperature. These algorithms determine the flow rate or temperature of the fluid that is circulated through the catheter based on the temperature history and instantaneous differential between the patient's desired temperature and the patients' actual temperature. The gain of the feedback control system is defined in terms of the power

extracted or delivered by the catheter per unit temperature differential between the patient's desired and actual temperature, which is also known as the servo error.

A common feedback control algorithm is incorporated in a PID (proportional-integral-derivative) controller. The parameters used by a PID controller include a gain factor, an integral factor, and a derivative factor to adjust the power transferred by the catheter to control the patients' temperature. An optimal feedback control algorithm should precisely control the patient's temperature by minimizing the system's error in response to a command, i.e. a desired temperature state. Depending on the patients' thermal environment, level of anesthesia, and the surgical manipulations performed on the patient, thermal disturbances are created. The task of the feedback control system is to add or subtract heat from the patient to balance out these thermal disturbances to achieve a neutral heat balance between the patient and his or her environment.

It is important that a proper feedback control gain factor be employed when cooling (or heating) a given body or organ. For example, if the selected gain is too high, the body's response to such a relatively rapid rate of cooling will be to overshoot the target temperature, which may induce a series of damped temperature oscillations about the target temperature. If the gain factor chosen is optimal, the body's response to a thermal disturbance or temperature command (a step change input to the control loop), will yield a response that is critically damped; i.e. in which there is minimal or no temperature overshoot or oscillations. If a low gain level is employed, the system response will be such that a much longer time will be required to achieve the desired steady state temperature value.

One critical parameter used in calculating the appropriate gain factor for the feedback controller is the mass of the body being cooled or heated. Other factors being equal, a greater mass will clearly require a larger gain factor than a smaller mass. Unfortunately, this is not an easy parameter to measure since the mass value that is needed is generally not the actual whole body mass but rather an effective thermal mass

that represents a smaller mass volume of the patient. Depending on the degree of vasoconstriction/dilation, the peripheral tissue beds are isolated from the core temperature compartments of the patient, thus reducing the mass that is cooled or heated by over 50%, depending on patient morphology. The optimal gain factor may vary by over a factor of ten from large to small patients with mixed levels of vasoconstriction/dilation. If a single gain factor based on a hypothetical average patient were to be used for all patients, the resulting system response may be very poor for large patients while significantly overshooting the target temperature in small patients.

Accordingly, it would be desirable to provide a method and apparatus for quickly and easily determining a patient's effective thermal mass used to calculate a feedback control gain factor that is employed to control the rate of heat transfer during the induction and maintenance of hypothermia.

Summary of the Invention

In accordance with the present invention, a method is provided for determining an effective thermal mass of a patient. The effective thermal mass is employed to determine a gain factor used in a feedback control system controlling patient temperature. The method begins by inducing hypothermia or hyperthermia in at least a selected portion of the patient with a device having a heat transfer surface. Next, power is transferred between the device and the patient. A change in temperature over time, which arises in the selected portion of the patient, is measured while performing the step of inducing hypothermia or hyperthermia. Finally, an effective thermal mass is calculated based on the measured power and the measured temperature change over time.

In accordance with one aspect of the invention, the selected portion of the patient in which hypothermia or hyperthermia is to be induced is an organ. Alternatively, the selected portion of the patient may be the whole body of the patient.

In accordance with another aspect of the invention, the device having a heat transfer surface is a catheter and hypothermia or hyperthermia is induced by introducing the catheter into a blood vessel supplying blood to the selected portion of the patient.

In accordance with yet another aspect of the invention a working fluid is circulated through the catheter and the power transferred between the catheter and the patient is measured by measuring a temperature differential between the working fluid as it enters the catheter and as it exits the catheter.

In accordance with another aspect of the invention, a computer readable medium is provided for determining an effective thermal mass of a selected portion of a patient in which hypothermia or hyperthermia is to be induced with a device having a heat transfer surface. The effective thermal mass is employed to determine a gain factor used in a feedback control system controlling patient temperature. The computer readable medium contains program instructions that, when loaded into a processor, cause the processor to store a measured value of power transferred between the device and the patient. The program instructions also cause the processor to store a measured value corresponding to a change in temperature over time, which arises in the selected portion of the patient while hypothermia or hyperthermia is being induced. Finally, the program instructions cause the processor to calculate and store an effective thermal mass based on the stored values of the measured power and the measured temperature change over time.

Brief Description of the Drawings

Figure 1 is a perspective view of one embodiment of a cooling catheter according to the invention.

Figure 2 is a longitudinal sectional view of the cooling catheter of Figure 1.

Detailed Description of the Invention

Figure 1 is a perspective view of an exemplary cooling catheter that may be employed in the method of the present invention. The cooling catheter 14 is comprised of a series of articulating segments or modules. As seen in Figure 1, a first articulating segment 20 is located at the distal end of the cooling catheter 14. A turbulence-inducing exterior surface 28 of the segment 20 is formed from one or more invaginations 26. Within the segment 20, the spiraling invaginations 26 rotate in a clockwise direction as they proceed towards the distal end of the cooling catheter 14. The segment 20 is coupled to a second segment 24 via a bellows section 22 to provide flexibility. The second segment 24 is formed from one or more spiraling invaginations 30. The spiraling invaginations 30 rotate in a counter-clockwise direction as they proceed towards the distal end of the cooling catheter 14. The segment 24 is followed by a third segment 20 having the clockwise invaginations 26. Thus, successive segments of the cooling catheter 14 alternate between having clockwise and counterclockwise invaginations. In addition, the rounded invaginations also allow the cooling catheter to maintain a relatively atraumatic profile in comparison to the use of ribs or fins, thereby minimizing the possibility of damage to the vessel wall. A cooling catheter may be comprised of 1, 2, 3 or more segments.

The exterior surface 28 of the cooling catheter 14 can be made from metal, and may comprise very high thermally conductive material such as nickel, thereby, facilitating heat transfer. Alternatively, other metals such as stainless steel, titanium, aluminum, silver, copper and the like, can be used, with or without an appropriate coating or treatment to enhance biocompatibility or inhibit clot formation. Suitable biocompatible coatings include, e.g., gold, platinum or polymer paralyene. The cooling catheter 14 may be manufactured by plating a thin layer of metal on a mandrel that has the appropriate pattern. In this way, the cooling catheter 14 may be manufactured inexpensively in large quantities, which is an important feature in a disposable medical device.

Figure 2 is longitudinal sectional view of the cooling catheter shown in FIG.1 taken along line 5-5. Once the cooling catheter 14 is in place, a working fluid such as saline or other aqueous solution may be circulated through the cooling catheter 14. Fluid flows up a supply catheter into an insulated inner coaxial lumen 40. At the distal end of the cooling catheter 14, the working fluid exits the inner coaxial lumen 40 and enters an outer lumen 46. As the working fluid flows through the outer lumen 46, heat is transferred from the working fluid to the exterior surface 28 of the cooling catheter 14. Because the cooling catheter 14 is constructed from highly conductive material, the temperature of the external surface 28 may reach very close to the temperature of the working fluid. In order to avoid the loss of thermal energy from the working fluid within the inner coaxial lumen 40, an insulating coaxial layer 42 may be provided within the cooling catheter 14. The insulating coaxial layer 42 is comprised of a non-thermally conductive material. For example, insulation may be achieved by creating longitudinal air channels in the walls of the insulating coaxial layer 42. Alternatively, the insulating coaxial layer 42 may be constructed of a non-thermally conductive material like polytetrafluoroethylene or other polymer.

One of ordinary skill in the art will recognize that the present invention may employ devices or catheters other than those shown in FIGs. 1 and 2. For example, some catheters may include a balloon or other structure for enhancing the surface area of the portion of the catheter through which heat is transferred.

As previously mentioned, control algorithms are sometimes used to control the rate at which heat is extracted from the body by the catheter. These algorithms may be embodied in hardware, software, or a combination of both. The gain factor employed by such algorithms is dependent on the effective thermal mass of the body or organ being cooled. Thus, it is important to determine the effective thermal mass so that an appropriate gain factor can be calculated for the feedback control algorithm.

The mass of the body (organ or whole body) being cooled can be estimated by relating the power removed by the catheter to the power lost by the body.

The power removed by the catheter may be expressed as follows:

$$P_{catheter} = Mc_f\Delta T \qquad (1)$$

Where M is the mass flow rate of the fluid circulating through the catheter (typically measured in terms of cc/s), c_f is the heat capacity of the fluid, and ΔT is the temperature difference between the working fluid as it enters the catheter and as it exits the catheter. Accordingly, $P_{catheter}$ can be readily calculated by measuring the mass flow of the circulating fluid and the temperature difference between the working fluid as it enters and exits the catheter.

The power removed by the catheter as determined by equation (1) may be equated to the power that is lost by the patient's body:

$$P_{catheter} = mc_b\partial T/\partial t \qquad (2)$$

Where $P_{catheter}$ is now the power lost by the patient's body and has the value calculated by equation (1), m is the effective thermal mass of the body being cooled, c_b is the heat capacity of the body, and $\partial T/\partial t$ is the change in temperature per unit time of the mass being cooled.

Accordingly, the effective thermal mass of the body being cooled is:

$$m = P_{catheter}/(c_b\partial T/\partial t) \qquad (3)$$

Since all the variables in equation (3) are either known or are measurable, the effective mass can be determined.

The mass calculated in this manner is an effective thermal mass that represents the portion of the body from which power is removed (i.e., the portion of the body that

is cooled). The temperature change in equation (3) represents the temperature change of the portion of the body being cooled. For example, if whole body cooling is to be performed, the change of the core body temperature may be measured to calculate mass in accordance with equation (3). In general, for whole body cooling, if the patient is vasoconstricted, the effective mass may represent about 50% of the total body mass. If the patient is vasodilated, the effective mass will be closer to the total body mass.

Alternatively, if only a selected organ such as the brain is to be cooled, then the temperature change that will be used in equation (3) would be the temperature change of the organ, assuming of course that the organ can be at least briefly considered to be largely thermally isolated from the remainder of the body. In this case the effective mass that is determined would be comparable to the mass of the organ. If the selected organ to be cooled is the brain, for example, the catheter is placed in the common carotid artery, the internal carotid artery, or both. The temperature changed used in equation (3) will be measured by inserting a temperature sensor into the brain or via a tympanic membrane sensor, both of which are commercially available.

Example

In an animal study, whole body cooling was accomplished by inserting the catheter through the femoral vein and then through the inferior vena cava as far as the right atrium and the superior vena cava. Cooling was initiated by circulating a working fluid at a flow rate of 5cc/sec. The temperature differential between the fluid entering the catheter and the fluid exiting the catheter was 17°C. Accordingly, the power extracted by the catheter was 354 watts.

The body core temperature was measured through the esophagus. Twenty minutes after cooling was initiated, the rate at which the core temperature changed was measured over a period of about ten minutes, resulting in an average temperature change of about 4°C/hr.

From equation (3) above, the effective thermal mass is:

$$m = 354 \text{ watts}/(.965 \text{watts/kg}\cdot C^{o})(10^{o}c/hr) = 37 \text{ kg}$$

The total mass of the animal was 53 kg, and thus the effective mass was found to be 69% of the total mass.

Although various embodiments are specifically illustrated and described herein, it will be appreciated that modifications and variations of the present invention are covered by the above teachings and are within the purview of the appended claims without departing from the spirit and intended scope of the invention. For example, while the cooling catheter has been described as a device that employs a circulating fluid, other types of catheters may alternatively be employed. For example, the catheter may employ a compressed refrigerant that is pumped through the catheter into an expansion element.